
PATENT
Docket No. 2026-4255

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicant(s) | : | Emerson, S.U. et al. | Group Art Unit: 1643 |
| Serial No. | : | 08/840,316 | Examiner: Zeman, M. |
| Filed | : | April 11, 1997 | |
| For | : | RECOMBINANT PROTEINS OF A PAKISTANI STRAIN OF HEPATITIS E AND THEIR USE IN DIAGNOSTIC METHODS AND VACCINES | |

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4-5-99

Assistant Commissioner for Patents
Washington, D.C. 20231

**AMENDMENT AND RESPONSE**

This Amendment is submitted in response to an Office Action dated November 17, 1998 in which the Examiner rejected claims 25-33 of this application. Reconsideration is respectfully requested in view of the following remarks.

Rejection Under 35 U.S.C. §102(b)

The Examiner rejected claims 25, 28 and 31-33 under §102(b) as being anticipated by Tsarev et al. (1996 in Enterically Transmitted Hepatitis Viruses, pages 373-383). In particular, the Examiner cites to disclosure in Tsarev et al. of a DNA encoding amino acids 112-609 of ORF2 and contends that the public availability date for the Tsarev et al. article is October 1995 as the article is contained in a book which is a compilation of articles presented at a symposium on October 16-17, 1995. It is therefore asserted that since "claims 25 and 28 are drawn to a DNA

molecule encoding from amino acid 112 to about amino acid 607" (page 2, Office Action, emphasis added), these claims (and dependent claims 31-33) are anticipated by Tsarev et al. With all due respect, Applicants disagree.

First, the rejected claims do not recite that the carboxy-terminii of the encoded protein is "about amino acid 607". Rather, the rejected claims recite that "the carboxy-terminii is an amino acid in the range of 578 to 607". Thus, the rejected claims encompass DNA molecules encoding a protein having its carboxy-terminii at amino acid 607.

Second, contrary to the Examiner's assertion, there is nothing in Tsarev that suggests that the ORF2 protein ends at "approximately amino acid 609". Rather, the cited Tsarev et al. article discloses a "112-609 amino acid ORF2 fragment" (page 378).

Thus, as Tsarev discloses a DNA which encodes amino acids 112-609, it cannot be held to anticipate the claimed DNA molecules.

However, while it is believed that claims 25-28 and 31-33 are not anticipated by Tsarev, Applicants submit the Declarations attached as Exhibits A and B in order to facilitate prosecution of this application to allowance.

Exhibit A is a Declaration by Lucy Curci-Gonzalez, Head Librarian at Morgan & Finnegan, L.L.P., which presents evidence that the book containing the Tsarev article was published on July 31, 1996, i.e. within one year of the effective filing date of this application.

Exhibit B is a Declaration by the named inventors which states (1) that the disclosure cited to by the Examiner does not correspond to the oral presentation at the symposium on October 16-17, 1995 in Paris, France, (2) that the disclosure of a DNA encoding

amino acids 112-609 of the HEV ORF2 protein was first made in the published article, and (3) that the co-inventors of this application are the co-authors of the Tsarev et al. article and that the other named authors, while making contributions such that authorship was warranted, did not make an inventive contribution to the subject matter claimed in this application. Thus, taken together, these Declarations establish that Tsarev et al. is not prior art under 35 U.S.C. §102. Accordingly, withdrawal of the §102(b) rejection is respectfully requested.

Rejections Of The Claims Under 35 U.S.C. §103(a)

The Examiner rejected claims 26, 27, 29 and 30 under §103(a) as being unpatentable over Tsarev as applied to claims 25, 28 and 31-33 in the §102(b) rejection. In particular, it is asserted that since Tsarev et al. disclose a DNA encoding amino acids 112-609 of HEV ORF2 and "suggests that other post-translation modifications may occur to the expressed protein (p378), which could include further C-terminal clipping" (page 4, Office Action), further modification to or shortening of the expressed 112-609 protein would have been routine optimization. With all due respect, Applicants disagree.

On the page cited to by the Examiner (page 378), Tsarev et al. merely disclose that "[T]he heterogeneity of the ~55kDa protein might result from other post-translational modifications". However, Tsarev et al. is completely silent as to what such "other post-translational modifications" might be.

There is simply nothing in Tsarev et al that teaches or suggests fixing the amino-terminus of the 112-609 ORF2 protein at amino acid 112 and then deleting only at the carboxy-terminal end of the protein.

Moreover, the further C-terminal clipping suggested by the Examiner (and not by the reference itself) is merely one modification of many that could be encompassed by the phrase "other post-translational modifications". For example, such a phrase could encompass glycosylation, further N-terminal clipping or a combination of further clipping at both the N- and C-terminii.

It is therefore Applicants' position that there was simply no motivation, other than the improper application of hindsight analysis, for the Examiner's assertion that it would be obvious to subject the 112-609 protein of Tsarev et al. to further C-terminal clipping to arrive at the specific 112-607 and 112-578 proteins encoded by the DNA molecules of rejected claims 26 and 27. Thus, at best, the Examiner is improperly using hindsight analysis in applying an "obvious to try" standard that has long been held not to constitute obviousness. In re O'Farrell, 7 U.S.P.Q.2d 1673 (Fed. Cir. 1988).

Nevertheless, as in response to the §102(b) rejection, Applicants again refer to the Declarations attached as Exhibits A and B in order to facilitate prosecution of the instant application to allowance. Since as discussed above, these Declarations establish that Tsarev et al. is not prior art to the claimed invention, withdrawal of the §103 rejection is respectfully requested.

In sum, in view of the above remarks, the instant application is believed to be in condition for allowance.

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Early and favorable consideration by the Examiner is respectfully solicited.

Respectfully submitted,

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